UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/027,725	12/21/2001	Sabine Flicker	25401-4	9787

24256 7590 11/19/2003

DINSMORE & SHOHL, LLP
1900 CHEMED CENTER
255 EAST FIFTH STREET
CINCINNATI, OH 45202

EXAMINER	
HUYNH, PHUONG N	
ART UNIT	**PAPER NUMBER**
1644	

DATE MAILED: 11/19/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/027,725	FLICKER ET AL.	
	Examiner	Art Unit	
	Phuong Huynh	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE One MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *6/11/02; 12/1/01*.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-24* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-24* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

13)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

a) ☐ The translation of the foreign language provisional application has been received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

I. The location of your application in the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Art Unit 1644, Group 1640, Technology Center 1600.

II. Claims 1-24 are pending.

III. It is noted that there are three clones (clone 60, 94 and 100) of allergen specific human IgE Fab and that the amino acid sequence of SEQ ID NO: 7 (heavy chain of clone 60) is encoded by the nucleic acid sequence of SEQ ID NO: 2, the amino acid sequence of SEQ ID NO: 8 (heavy chain of clone 94) is encoded by the nucleic acid sequence of SEQ ID NO: 1, and the amino acid sequence of SEQ ID NO: 9 (heavy chain of clone 100) is encoded by the nucleic acid sequence of SEQ IDNO: 3. However, it is not clear which amino acid sequence of the light chain such as SEQ ID NO: 10-12 encoded by which nucleic acid sequence such as SEQ ID NO: 4-6 goes with which clone. Therefore, Applicant is required to elect a specific combination of the specific amino acid sequence for the light chain, the corresponding nucleotide sequence for the light chain, the specific amino acid sequence for the heavy chain and the corresponding nucleic acid for the specific human IgE Fab. The restriction has been set forth for each as a separate group, irrespective of the format of the claims.

Election/Restrictions

IV. Restriction to one of the following inventions is required under 35 U.S.C. 121:

1. Claims 1-20, drawn to Group 2 allergen specific human IgE Fab having the specific amino acid sequence of SEQ ID NO: 7 (heavy chain) encoded by the nucleic acid sequence of SEQ ID NO: 2, the specific light chain having the specific amino acid sequence such as SDEQ ID NO: 10-12 encoded by the specific nucleic acid sequence such as SEQ ID NO: 4-6 or an essentially homologous variant thereof, a diagnostic kit comprising said IgE Fab, a vaccine comprising said IgE Fabs, classified in Class 424, subclass 130.1; Class 530, subclass 387.1.

2. Claims 1-20, drawn to Group 2 allergen specific human IgE Fab having the specific amino acid sequence of SEQ ID NO: 8 (heavy chain) encoded by the nucleic acid sequence of SEQ ID NO: 1, the specific light chain having the specific amino acid sequence such as SEQ ID NO: 10-12 encoded by the specific nucleic acid sequence such as SEQ ID NO: 4-6 or an essentially homologous variant thereof, a diagnostic kit comprising said IgE Fab, a vaccine comprising said IgE Fabs, classified in Class 424, subclass 130.1; Class 530, subclass 387.1.

3. Claims 1-20, drawn to Group 2 allergen specific human IgE Fab having the specific amino acid sequence of SEQ ID NO: 9 (heavy chain) encoded by the nucleic acid sequence of SEQ ID NO: 3, the specific light chain having the specific amino acid sequence such as SEQ ID NO: 10-12 encoded by the specific nucleic acid sequence such as SEQ ID NO: 4-6 or an essentially homologous variant thereof, a diagnostic kit comprising said IgE Fab, a vaccine comprising said IgE Fabs, classified in Class 424, subclass 130.1; Class 530, subclass 387.1.

4. Claim 21, drawn to a method for passive immunotherapy comprising administering Phl1 p2-specific IgE-Fab having the amino acid sequences for heavy (SEQ ID NO: 7) and the specific light chain such as SEQ ID NO: 10-12, classified in Class 424, subclass 130.1.

5. Claim 21, drawn to a method for passive immunotherapy comprising administering Phl1 p2-specific IgE-Fab having the amino acid sequences for heavy (SEQ ID NO: 8) and the specific light chain such as SEQ ID NO: 10-12, classified in Class 424, subclass 130.1.

6. Claim 21, drawn to a method for passive immunotherapy comprising administering Phl1 p2-specific IgE-Fab having the amino acid sequences for heavy (SEQ ID NO: 9) and the specific light chain such as SEQ ID NO: 10-12, classified in Class 424, subclass 130.1.

7. Claim 22, drawn to a method for diagnosing type I allergy using Phl p2-specific IgE-Fab Phl1 p2-specific IgE-Fab having the amino acid sequences for the specific heavy (SEQ ID NO: 7) and the specific light chain such as SEQ ID NO: 10-12, classified in Class 435, subclass 7.1

8. Claim 22, drawn to a method for diagnosing type I allergy using Phl p2-specific IgE-Fab Phl1 p2-specific IgE-Fab having the amino acid sequences for the specific heavy (SEQ ID NO: 8) and the specific light chain such as SEQ ID NO: 10-12, classified in Class 435, subclass 7.1.

9. Claim 22, drawn to a method for diagnosing type I allergy using Phl p2-specific IgE-Fab Phl1 p2-specific IgE-Fab having the amino acid sequences for the specific heavy (SEQ ID NO: 9) and the specific light chain such as SEQ ID NO: 10-12, classified in Class 435, subclass 7.1.

10. Claim 23, drawn to a method for environmental allergen detection using Phl p-specific IgE-Fab having the amino acid sequences for the specific heavy (SEQ ID NO: 7) and the specific light chain such as SEQ ID NO: 10-12, classified in Class 435, subclass 7.92.

11. Claim 23, drawn to a method for environmental allergen detection using Phl p-specific IgE-Fab having the amino acid sequences for the specific heavy (SEQ ID NO: 8) and the specific light chain such as SEQ ID NO: 10-12, classified in Class 435, subclass 7.92.

12. Claim 23, drawn to a method for environmental allergen detection using Phl p-specific IgE-Fab having the amino acid sequences for the specific heavy (SEQ ID NO: 9) and the specific light chain such as SEQ ID NO: 10-12, classified in Class 435, subclass 7.92.

13. Claim 24, drawn to a method for standardization of allergen extracts using Pl1 p2-specific IgE-Fabs, having the amino acid sequences for the specific heavy (SEQ ID NO: 7) and the specific light chain such as SEQ ID NO: 10-12, classified in Class 436, subclass 512.

14. Claim 24, drawn to a method for standardization of allergen extracts using Pl1 p2-specific IgE-Fabs, having the amino acid sequences for the specific heavy (SEQ ID NO: 8) and the specific light chain such as SEQ ID NO: 10-12, classified in Class 436, subclass 512.

15. Claim 24, drawn to a method for standardization of allergen extracts using Pl1 p2-specific IgE-Fabs, having the amino acid sequences for the specific heavy (SEQ ID NO: 9) and the specific light chain such as SEQ ID NO: 10-12, classified in Class 436, subclass 512.

The inventions are distinct, each from the other because of the following reasons:

Inventions of Groups 1-3 are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the different products as claimed differ with respect to their structure, and binding specificity. Therefore, they are patentably distinct.

Inventions of Groups 4-15 are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the methods of treating, diagnosing and detecting using distinct product differ with their respect to their process steps and endpoints. Therefore, they are patentably distinct.

Inventions of Groups (1-3) and Groups (4-15) are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the products as claimed can be used in materially different process such as screening assays. Therefore, they are patentably distinct.

V. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification and/or recognized divergent subject matter. Further, even though in some cases the classification is shared, a different field of search would be required based upon the structurally distinct products recited and the various methods comprising the distinct method steps. Therefore restriction for examination purposes as indicated

is proper. Further, a prior art search also requires a literature search. It is an undue burden for the examiner to search more than one invention.

VI. Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed.

VII. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between products claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai, In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

VIII. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Phuong Huynh "NEON" whose telephone number is (703) 308-4844. The examiner can normally be reached Monday through Friday from 9:00 am to 5:30 p.m. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (703) 308-3973. Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center 1600 receptionist whose telephone number is (703) 308-0196.

IX. Papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform to the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center telephone number is (703) 305-3014.

Phuong N. Huynh, Ph.D.
Patent Examiner
Technology Center 1600
November 17, 2003

Christina Chan

CHRISTINA CHAN
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600